K122284 (pg 1/2)

OCT 24 2012

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Hoffmann 3 Modular External Fixation System
Common Name:	External Fixation System
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Regulatory Class:	Class II
Product Codes:	87 KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Components
For Information contact:	Estela Celi, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-6038 estela.celi@stryker.com
Date Prepared:	July 27, 2012

Description:
This Traditional 510(k) submission is intended to address the addition of new components to the previously cleared Hoffmann 3 Modular External Fixation System. The Hoffmann 3 Modular External Fixation System consists of Rods, Posts, Couplings, Clamps and Pins that can be combined to construct different frame configurations that are MR conditional. The additional components consist of a Multiplanar Rod to Rod Coupling, Multiplanar Pin to Rod Coupling, 30° Rod Coupler, 4/5 Apex Pin, 5/6 Transfixing Pin and a Ø11mm Semi Circular Rod. This external fixation system may also be used with the components in other Howmedica Osteonics external fixation systems such as the Hoffmann II MRI and Hoffmann II Compact MRI External Fixation Systems and in conjunction with other commercially available Apex Pins.

Intended Use:
The Hoffmann 3 Modular External Fixation System is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

Indications:
The Hoffmann 3 Modular External Fixation System components are external fixation frame components for use with the components of the Hoffmann II MRI and Hoffmann II Compact MRI External Fixation Systems, in conjunction with Apex Pins. It is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

The indications for use of external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

Summary of Technologies:

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate devices:

- K111786 Hoffmann 3 Modular External Fixation System
- K051306 Hoffmann II MRI External Fixation System
- K053472 Hoffmann II MRI Components
- K001886 Apex Fixation Pins (reference predicate)

Non-Clinical Testing:

Non-clinical laboratory testing and engineering evaluations were performed for the Hoffmann 3 System components to determine substantial equivalence. Testing demonstrated that the subject Hoffmann 3 System components are substantially equivalent to devices currently cleared for marketing.

The following testing and evaluations were performed:

- Corrosion Testing
- Insertion Testing
- Pullout Strength Testing
- Rotation Testing
- Static and Dynamic Cantilever Bending Testing

Magnetic Resonance Environment Testing

- Radio Frequency Heating Testing
- Force and Torque Testing
- Artifact Testing

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The Hoffmann 3 System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporated
% Ms. Estela Celi
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

OCT 24 2012

Re: K122284
Trade/Device Name: Hoffman 3 Modular External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: July 27, 2012
Received: July 30, 2012

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122284 (pg 1/1)

Device Name: Hoffmann 3 Modular External Fixation System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic and Restorative Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K122284